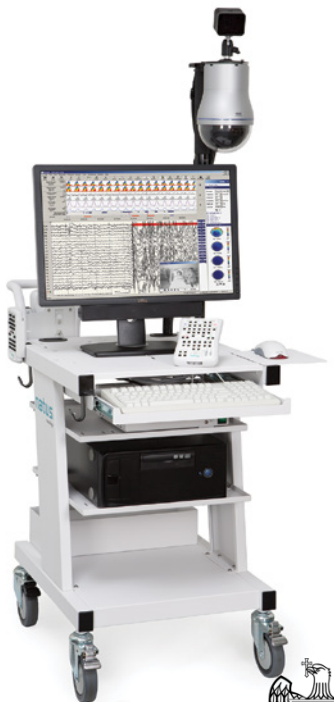
NicoletOne vEEG System

A cost effective value EEG system

The NicoletOne vEEG system offers excellent value without compromising quality. This system delivers essential features for efficient performance, making it ideal for your clinical needs.

The NicoletOne vEEG system offers all the features of sophisticated EEG systems such as photic stimulation, timers for hyperventilation, data remontaging, reports and more. It can also be enhanced with a number of optional add-on packages including digital video, spike and seizure detection or sleep analysis.



Flexible Options

Synchronous Video: Up to 640 x 480 resolution.

Spike and Seizure Detection: Online and offline Spike and Seizure detection with user configurable parameters. Spike sensitivity can be modified post acquisition via a slider control, quickly displaying the resulting changes.

Trend Analysis: Offline and online trend analysis. Envelope, total power, absolute band power, relative band power, amplitude integrated EEG, spectral edge and spectrogram. Unlimited number of simultaneous trends. Individual filter settings for each trend.

Topographic Brain Maps: Band Power, Coherence & Amplitude maps.

Remote Control: Control a recording session remotely. Provides all the functionality of the acquisition program on a Review System connected via Local Area Network (LAN).

Remote Review: Remotely review data over the Internet using a Citrix server to make timely patient care-related decisions

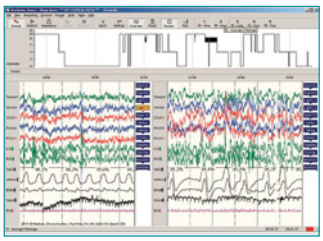
Sleep Analysis: Transform your system into a fully-functional polysomnography system.

NicVue Connect HL7: Package seamlessly connects diagnostic equipment to the Hospital Information System (HIS).

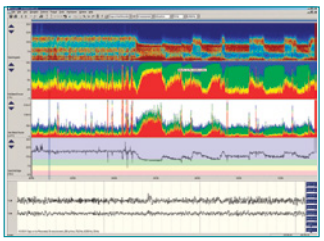
natus®

NicoletOne vEEG System

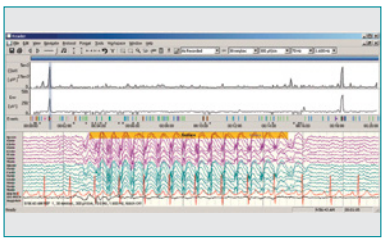
NicoletOne vEEG Features



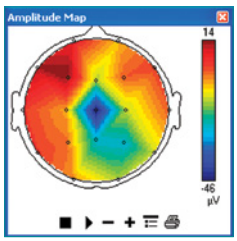
Recording Screen



Trend Screen



Trends/Seizure Screen



Amplitude Map Screen

vEEG Amplifiers and Headboxes

Field-tested, rugged and reliable

Feature: Passive headbox with glow-in-the-dark overlay
Benefit: For ease of use in darkened environments

Feature: Integrated Impedance Display
Benefit: See your impedance value right at the bedside

Feature: Integrated SpO_2
Benefit: Added value with SpO_2 enabling sleep monitoring

Feature: Ethernet Amplifier Interface
Benefit: Industry-standard connection

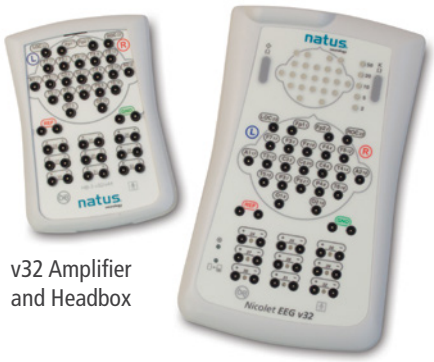
Feature: 9 Auxiliary pair (AC or DC)
Benefit: Ability to connect devices such as respiratory belts, thermistors, etc

Feature: Patient Event Button
Benefit: System software creates entries in the event list

Feature: One High Level DC Input (v32 only)
Benefit: Abililty to connect various devices such as CPAP

Feature: 12 High Level DC Inputs (v44 only)
Benefit: Ability to connect multiple devices such as CPAP

v44 Amplifier and Headbox



v32 Amplifier and Headbox

Natus support

At Natus, we strive for excellence in customer and technical service.

Here's how we can help:

- Accessible and effective Technical Support
- Definitive technical documentation and knowledgeable installation teams
- Replacement unit and spare part availability
- Extended warranty and service coverage programs
- Comprehensive, flexible customer training courses

EEG and ICU Supplies solutions

Convenient, complete, trusted

Natus supports the full spectrum of EEG and ICU care, providing a complete portfolio of supplies for a seamless solution.

- Dedicated and knowledgeable customer support
- Streamlined order processing
- Convenient online ordering (US Customers only)
  Natus Medical Store – natusmedicalstore.com

To learn more about Natus products contact your local distributor or sales representative.

US Customers call: **1-800-356-0007**

International Customers call: **+1-608-829-8500**

Healthcare solutions with one thing in mind. You.

natus®

Natus Medical Incorporated

natus.com

Natus® NeuroWorks® Routine EEG Solutions

High-quality EEG in a dependable system

natus®

Natus® NeuroWorks® Routine EEG Solutions

EEG solutions

A powerful solution, rich with dynamic features that provide the tools you need in any environment – EEG lab, operating room, emergency room, private practice clinic, outpatient or EEG service provider.

Reliable performance – Exceptional signal quality with high sample rates and HD video

Setup flexibility – True TCP/IP amplifiers and cameras with DHCP support plug and play anywhere on the network

Enhanced patient mobility and comfort – Small, lightweight patient-wearable amplifiers

Security & HIPAA compliance – XLSecurity role-based HIPAA compliance package with Active Directory integration and encryption

Natus NeuroWorks software

Industry leading software with an extensive and flexible feature set for a variety of environments

Leading-edge software that provides an intuitive clinical experience

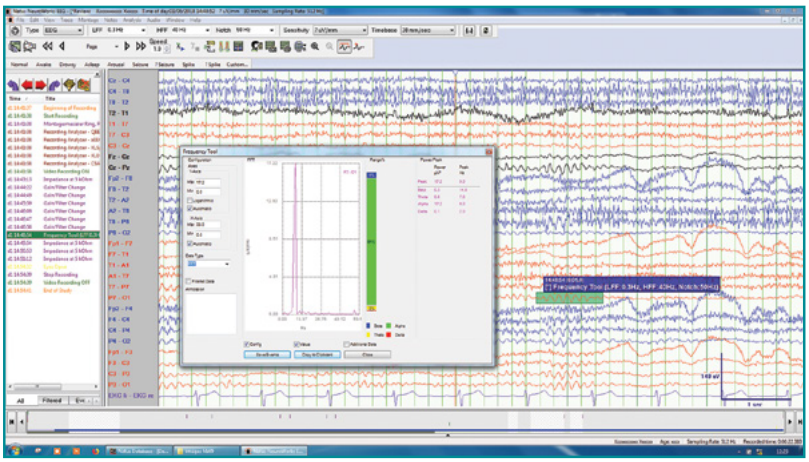
- Windows® 10 compatible
- Multiple spike and event analysis options, plus many additional Advanced Trending options
- Automated data recovery while operating the Bovie/Electrocautery in the Operating Room
- Fully synchronized, easy to set up, Full HD (1080p) TCP/IP PTZ network cameras
- Data sharing in multi-site environments

Time-saving administrator functions

- Easy setup using IP streaming cameras and amplifiers
- Automated discovery of amplifiers and cameras
- Automated settings synchronization across networked NeuroWorks stations

Security and peace of mind for IT professionals and clinicians working together

- XLSecurity Layer with role-based security package and drive encryption
- Searchable and powerful enterprise level SQL server distributed database
- Bi-directional HL7 integration with HIS/EMR
- Automated software installation for large sites with Cerebrum Enterprise Solution



Frequency Analysis Tool

- Drag the area of interest
- Quickly identify frequency, amplitude and power for selected data
- Display percent for each frequency range

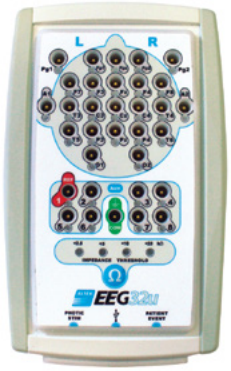
Natus cybersecurity program

Proactively addressing cybersecurity as an integral part of our design process

- Secure handling of confidential information generated or maintained by our hardware and software
- Continuous evaluation of our products against identified threats and vulnerabilities
- Monitoring of feedback channels to manage security events in the field

Natus NeuroWorks EEG hardware

Durable, reliable, high-quality amplifiers for dependable data acquisition



EEG32U

Simple to use amplifier designed for routine EEG studies

- 32-channel amplifier
- Up to 1024 Hz sampling rate
- On-board impedance check
- 10-20 head stamp with impedance LEDs
- Only one standard USB cable from PC to amplifier for data and power transmission

Natus Brain Monitor*

Versatile amplifier expandable for different testing options

- 64 referential, 16 DC channels
- 4 kHz sampling rate
- Integrated pulse oximeter
- Touchscreen display on base unit with real time interaction with ongoing studies
- Visual impedance checking and adding notes
- Perform bio-calibrations from the patient bedside

*requires NeuroWorks 9.0 or higher

Natus LED Photic Stimulator

- Eliminates acoustic and electrical interference
- Customized photic sequences
- Easy to start or stop photic series

Natus® NeuroWorks® Routine EEG Solutions

Data security

Set up individual user or group access and permissions for the system and within the application. Assign separate lock-down rules for different computers on the same network. Access Audit Logs to review user activity on the system. Security is integrated with Microsoft® Active Directory and peace of mind is enhanced with system encryption.

EEG Supplies solutions

Convenient, complete, trusted

Natus supports the full spectrum of EEG care, providing a complete portfolio of EEG supplies for a seamless solution.

- Dedicated and knowledgeable customer support
- Streamlined order processing
- Convenient online ordering (US Customers only)
  Natus Medical Store – natusmedicalstore.com

Service

At Natus, we strive for excellence in customer and technical service.

Here's how we can help:

- Accessible and effective Technical Support
- Definitive technical documentation and knowledgeable installation teams
- Optional extended warranty and service coverage programs
- Comprehensive, flexible customer training courses

To learn more about Natus products contact your local distributor or sales representative.

US Customers Call: **1-800-356-0007**

International Customers Call: **+1-608-829-8500**

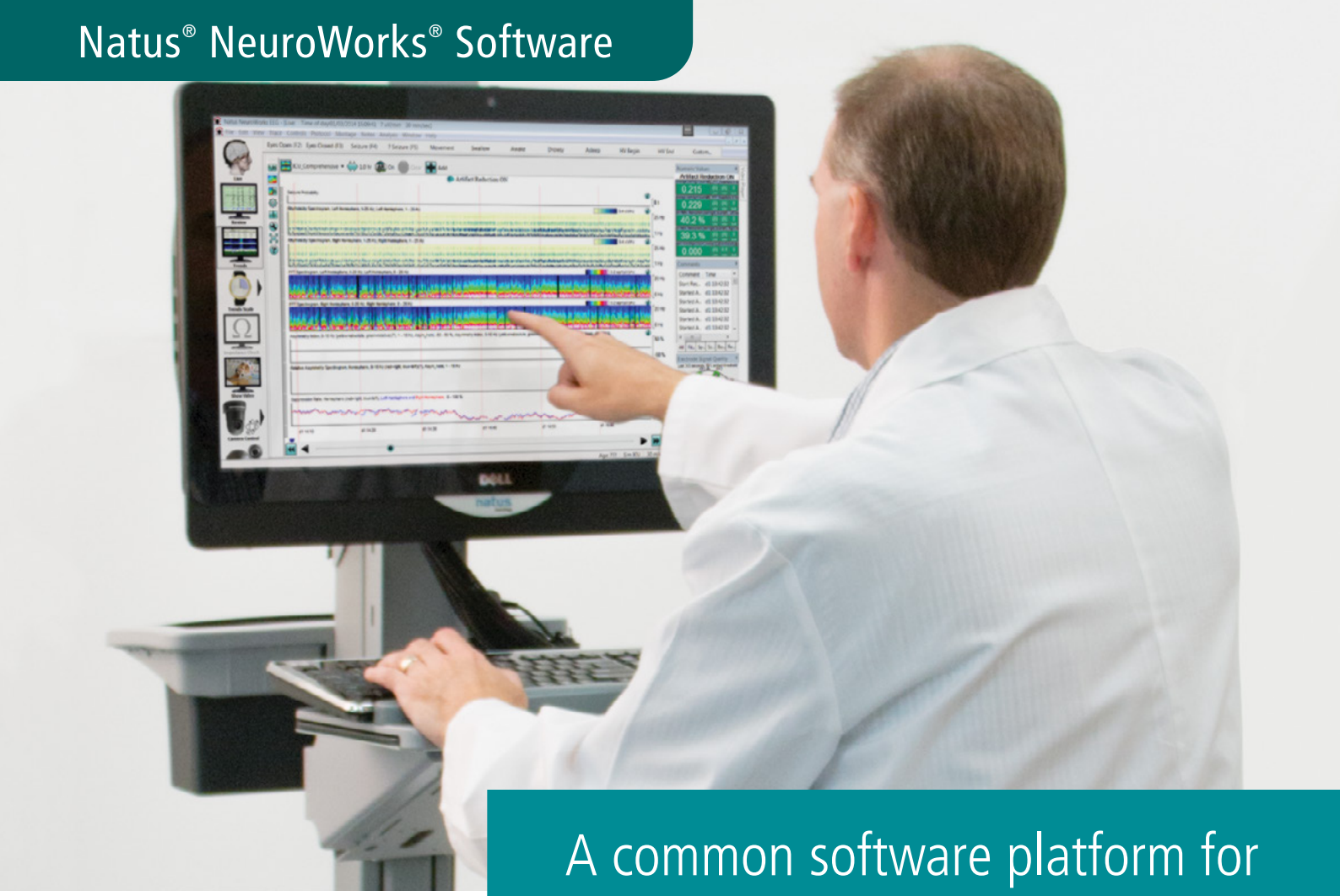
Healthcare solutions with one thing in mind. You.

natus®

Natus Medical Incorporated

natus.com

Natus® NeuroWorks® Software



A common software platform for EEG, Sleep and research studies

What's new in NeuroWorks

- Advanced Trending
- Physiological Monitoring Integration
- Support for new LTM data management
- Improved display of annotations and navigation to regions of interest across a set of studies
- Windows® 10 compatibility
- Support for Quantum on-board memory and Nicolet Cortical Stimulator integrations
- Support for new cutting-edge Brain Monitor
- Frequency Analysis Tool
- Addition of Full HD (1080p) video

The Natus NeuroWorks platform simplifies the process of collecting, monitoring and managing data for routine EEG testing, long-term monitoring (LTM), ICU monitoring, ambulatory and Sleep studies. NeuroWorks systems are scalable to meet the needs of private practice clinics, hospitals and large teaching facilities.

Intuitive clinical experience

- Multiple Spike & Event analyzer options
- Fully synchronized HD video
- Monitoring options for home ambulatory studies
- Scalable remote access with Citrix provisioning
- Powerful qEEG trending

Time-saving administrator functions

- Ease of setup using IP streaming cameras and amplifiers
- Powerful enterprise level SQL database
- Automated discovery of amplifiers and cameras using DHCP

Streamlined workflow

- Easy data searching with a variety of customizable parameters
- Automated settings synchronization across networked NeuroWorks stations
- Convenient import and export with EDF/EDF+
- Data sharing in multi-site environments

natus®

Natus® NeuroWorks® Software

NeuroWorks configures to your network and security needs

Robust Security Features

- HIPAA requirements via dedicated XLSecurity layer
- Role-based security access to features and studies
- Automated power recovery
- Microsoft® BitLocker™ drive encryption support

Advanced IT Capabilities

- Bi-directional HL7 integration with HIS/EMR
- Citrix® and VMWare® Ready partner – the most powerful infrastructure to facilitate collaboration

A cutting-edge, single solution for EEG and Sleep Studies

Advanced software for clinical excellence

- EEG/Sleep combo software package
- User customizable personal workspaces
- Software Development Kit for direct data access for research
- Data-Stream Wizard with two data streams for efficient clinical and research workflow*

Reliable and flexible hardware options

- Patient wearable compact and lightweight amplifiers
- Range of EEG amplifiers with 32- to 256- channels, plus differential and DC channel options
- Wireless amplifier options for long-term monitoring
- Range of sampling rates from 200 Hz to 16 kHz
- Perform EEG recordings in DC mode**
- Advanced Digital Trigger Input (up to 256 trigger values)**

A family of amplifiers to meet your needs

NEW! Natus Quantum

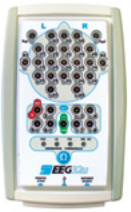
EMU40EX

NEW! Natus Brain Monitor

Trex HD Monitoring

Nicolet® v32

Nicolet® v44



EEG32U

Trex HD

To learn more about Natus products contact your local distributor or sales representative.

US Customers Call: **1-800-356-0007**

International Customers Call: **+1-608-829-8500**

*Only available with Quantum

**Only available with Quantum and Natus Brain Monitor

Healthcare solutions with one thing in mind. You.

natus®

Natus Medical Incorporated

natus.com

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 618069**

Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

In respect of:

Design and Manufacture of EMG Devices and Sterile and Non-sterile EMG/EEG Electrodes. Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of Microelectrode Cables.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-11-13** Date: **2019-11-19** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 618069

Issued To:

Natus Manufacturing Limited
IDA Business Park
Gort
Co. Galway
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102 MD 0106	Teca MyoJect Luer Lock Needle Electrodes Bo-ject Disposable Hypodermic Needle Electrodes	---
MD 0106	Teca Elite Disposable Concentric Needle Electrodes Teca Elite Disposable Monopolar Needle Electrodes Teca Disposable Monopolar Needle Electrodes Dantec DCN Disposable Concentric Needle Electrodes Value Line DCN Disposable Concentric Needle Electrodes	---
MD 1103	Clavis	---
MD 1103 MD 1301	Keypoint Focus Keypoint G4 Leadpoint Focus	---
Class Is		
MD 1301	Neuro MER Cables	---

First Issued: **2014-11-13** Date: **2019-11-19** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 618069**
Date:	**2019-11-19**
Issued To:	**Natus Manufacturing Limited** **IDA Business Park** **Gort** **Co. Galway** **Ireland**

Subcontractor:	**Service(s) supplied**
Golden Bridge Electech Inc. Hsin Feng Lu Don, Hsin Cheng Dist., Shijie town, Dong Guan City, Guang Dong, China	**Manufacture**
Medisize Ireland Ltd High Road, Letterkenny, Co. Donegal, Ireland	**Packaging**
Paul E. Danchell A/S Lyngvej 8 Jyderup 4450 Denmark	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 618069**
Date:	**2019-11-19**
Issued To:	**Natus Manufacturing Limited** **IDA Business Park** **Gort** **Co. Galway** **Ireland**

Subcontractor:	**Service(s) supplied**
SteriPack Medical Poland Sp. z o.o. also registered under S.M.P. Sp. z o.o. Łęg, ul, Japońska 1 55-220 Jelcz-Laskowice Poland	**Packaging**
Synergy Health Westport Ltd (Synergy Health - AST - Westport) Lodge Road Westport County Mayo Ireland	**Gamma Sterilization**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618069**
Date: **2019-11-19**
Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

Date	Reference Number	Action
13 November 2014	8195302	Initial Issue.
26 February 2014	8285252	Change of address to include "Co. Galway".
21 June 2018	8894466	Rewording of scope due to addition of new device to: " Design and Manufacture of EMG Devices and Sterile and Non-sterile EMG/EGG Electrodes. Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of Microelectrode Cables." Addition of new subcontractors: - Paul E Danchell A/S - Golden Bridge Electech Inc. - SteriPack Medical - Sp Medical - Medisize
17 December 2018	8862798	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618069**
Date: **2019-11-19**
Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

Date	Reference Number	Action
Current	9774582	Certificate Renewal. Removal of subcontractor 'SP Medical Sp.z.o.o'. Amendment to name of subcontractor Medisize to Medisize Ireland Ltd. Amendment to name and address of SteriPack Medical Poland Sp. z.o.o. Japonska 1, Leg, ul, Jelcz-Laskowice 55-220, Poland to SteriPack Medical Poland Sp. z o.o. also registered under S.M.P. Sp. z o.o., Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, Poland and Synergy Health Westport Ltd, Lodge Road, Westport, County Mayo, Ireland to Synergy Health Westport Ltd (Synergy Health – AST – Westport), Lodge Road, Westport, County Mayo, Ireland. Addition of Device Table.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01995**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

In respect of:

The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-07-07** Date: **2018-07-02** Expiry Date: **2023-07-06**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01995**
Date:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

Subcontractor:	**Service(s) supplied**
Creation Technologies 6820 Creditview Road Mississauga Ontario L5N OA9 Canada	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**Manufacture**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01995**
Date:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

Subcontractor:	**Service(s) supplied**
Natus Neurology Incorporated 3150 Pleasant View Road Middleton Wisconsin 53562 USA	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

Date	Reference Number	Action
07 July 1998	-	First Issued
31 August 1999	-	Extension to scope, Change of address
24 September 1999	-	Extension to scope
23 November 2000	-	Extension to scope
14 October 2003	-	Five year renewal, reissue in new format
30 April 2008	7199407	Certificate renewal
16 December 2008	7292967	Change of company name from Excel-Tech Ltd. (XL TEK) to Natus Medical Incorporated, DBA Excel-Tech Ltd. (XL TEK)
25 November 2011	7635138	Re-issue due to addition of significant subcontractors as below: - Braintronics BV, The Netherlands - Manufacture - EB Neuro S.r.P Italy, - Manufacture - Creation Technologies, Canada – Manufacture - Natus Europe Gmbh (Planegg), Germany - EU Rep. and Manufacture
01 July 2013	7972894	Certificate renewal

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

Date	Reference Number	Action
20 December 2013	8091741	Addition of subcontractor Astro-Med Inc, Greenwich Ave, W.Warwick, RI. Extension and scope clarification was 'The design, development, manufacture and installation of systems for the diagnosis and monitoring of electrophysiological signals' now 'The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.'
04 November 2014	8244952	Addition of significant subcontractor Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive, Appleton. Wisconsin, 54911, USA for manufacture.
18 March 2016	8471779	Removal of significant subcontractors Astro-Med Inc located in Rhode Island, Braintronis BV located in The Netherlands and EB Neuro SpA located in Italy.
04 November 2016	8623295	Removal of significant subcontractor Natus Europe GmbH. Addition of Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland as EU Representative.
26 April 2017	8728517	Addition of Subcontractor Natus Neurology Incorporated for manufacture.
Current	8995712	Renewal Addition of manufacturing activities to Natus- Ireland

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 592232**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

In respect of:

Design and manufacture of Electro-Neurophysiologic Diagnostic and Monitoring Devices and Sterile and Non-Sterile Invasive Electrodes.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-12** Date: **2018-06-29** Expiry Date: **2023-07-01**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Ad-Tech Medical Instrument Corp. 400 West Oakview Parkway Oak Creek Wisconsin 53154 USA	**Manufacture**
Chalgren Enterprises, Inc 380 Tomkins Court Gilroy California 95020 USA	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**
Paul E. Danchell A/S Lyngvej 8 Jyderup 4450 Denmark	**Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	**ETO Sterilization**
Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 592232**

Date: **2018-06-29**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

Date	Reference Number	Action
12 February 2013	7909188	Transfer from another Notified Body. The legal manufacturer, Natus Neurology Incorporated, is also known as Natus Medical Incorporated, CareFusion 209, Inc., VIASYS NeuroCare, VIA SYS Healthcare, Nicolet Biomedical, Nicolet Vascular
18 June 2013	7999455	Certificate renewal, and removal of Jabil Circuit Inc as significant subcontractor.
17 December 2013	8030396	Reissue due to change of company address from '1850 Deming Way, Middleton, WI 53562, USA' to '3150 Pleasant View Road, Middleton, WI 53562, USA' Addition of, 'Natus Neurology Incorporated, 1850 Deming Way, Middleton, Wisconsin, 53562, USA', for services of Design, Manufacture, Control of Sterilization and Regulatory Compliance. Change of subcontractor name from 'Natus Nicolet Ireland Ltd also trading as CareFusion Manufacturing Ireland 241 Limited' to 'Natus Manufacturing Limited'.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 592232**

Date: **2018-06-29**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

Date	Reference Number	Action
06 February 2015	8270322	Removal of the following significant subcontractors Transpack Medical Ltd for Packaging, Synergy Health Sterilisation UK Ltd for Gamma Irradiation, Medline Industries Inc for ETO Sterilization and SGM d.o.o for Manufacture, Natus Neurology Incorporated for Control of Sterilization, Design, Manufacture and Regulatory Compliance . Addition of significant subcontractor Paul E. Danchell A/S for Manufacture
08 November 2016	8603325	Change of EU Representative from Natus Europe GmbH, Robert-Koch-Str 1, 82152 Planegg, Germany to Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland. Removal of the following significant subcontractors Medisize Ireland Ldt for Packaging and Synergy Health Westport Ltd for Gamma Sterilization.
Current	8907455	Certificate renewal. Rewording of scope to remove "Non-Imaging Ultrasound Devices for Diagnosis and Monitoring of Vascular Flow." Change in address of subcontractor Ad-Tech. Removal of subcontractor Medizintechnik Basler AG.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Natus Medical Incorporated
5900 First Avenue South
Seattle
Washington
98108
USA

Holds Certificate No: **FM 702798**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and service of Medical Devices, including: Phototherapy lights (fluorescent, fiberoptic, LED), support - patient position, holder infant position, infant scales, pasteurizers washers, cerebral function monitor (electroencephalograph), pad neonatal eye, spectroradiometers, temperature probes, hearing protectors, protective restraint cooling caps for infants, products for the quantitative assessment and rehabilitation of balance disorders, and electroencephalograph systems, evoked response systems, otoacoustic emissions systems, hearing screeners and audiometers. Distributor of oral care kits, blood lancets and electrodes (ECG and CFM/EEG).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-11-11
Effective Date: 2019-01-18
Latest Revision Date: 2019-02-28
Expiry Date: 2022-01-17

...making excellence a habit.™

Natus Medical Incorporated
DBA Excel-Tech Ltd. (Xltek)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1, Canada
T 905.829.5300, 1.800.387.7516
F 905.829.5304, 1.800.404.2992
www.natus.com

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC as Amended by 2007/47/EC

CE 2797

Declaration Number: QMS-000163, Rev ZF
Product Name: Electroencephalograph and Polysomnography Product Family
GMDN Code: Please find in below table
EMDN Code: Please find in below table
Product Model Number and Description:

Product Description	***Model Numbers***	***GMDN***	***EMDN***
NeuroWorks / SleepWorks Software	104196, 002419, 004729, 022413, 022415, 022417, 022419, 024494, 024496, 024500, 024502, *034877*	*11467*	*Z12100382*
Gridview Software	SL-GRIDVIEW, SLU-GRID, DOC-CD-GRIDVIEW-EN-0, DOC-CD-GV20-EN-0	*11467*	*Z12100382*
EEG32U	10399 , PK1088	*11467*	Z121003
TrexHD	008043, 010382, PK1055HD	*11467*	Z12040380

Natus Medical Incorporated hereby declares that the above medical devices which bear the CE Mark are in conformity with the applicable requirements of EC Directive 93/42/EEC with amendments up to 2007/47/EC as enforced in the national laws of the European Union member states.

Classification/Rule: Class IIa, by Annex IX, Rule 10
Conformity Assessment Route: Annex II (excluding section 4)

This declaration is based on Certification of a full Quality Assurance System and compliance to the Medical Device Directive.

Certificate No.: CE 01995
Issued by: BSI Group The Netherlands B.V. (No 2797)
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam,
Netherlands
Expiry Date: 06 July, 2023

Additionally: Natus hereby declares, under its sole responsibility as Legal Manufacturer and not evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Commission Delegated Directive 2015/863 of 31 March

2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. It has been demonstrated that the requirements specified in Annex II of Directive 2015/863 have been met.

This declaration of conformity is valid from 28 Feb 2022.

EU Authorized Representative:
Natus Manufacturing Limited
IDA Business Park
Gort, Co. Galway, Ireland

Signature: _____ **Date** 28 Feb 2022

Sanjay Mehta
Director Global Regulatory Affairs, QARA

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01995**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

In respect of:

The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-07-07** Date: **2018-07-02** Expiry Date: **2023-07-06**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01995**
Date:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

Subcontractor:	**Service(s) supplied**
Creation Technologies 6820 Creditview Road Mississauga Ontario L5N OA9 Canada	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**Manufacture**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01995**
Date:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

Subcontractor:	**Service(s) supplied**
Natus Neurology Incorporated 3150 Pleasant View Road Middleton Wisconsin 53562 USA	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

Date	Reference Number	Action
07 July 1998	-	First Issued
31 August 1999	-	Extension to scope, Change of address
24 September 1999	-	Extension to scope
23 November 2000	-	Extension to scope
14 October 2003	-	Five year renewal, reissue in new format
30 April 2008	7199407	Certificate renewal
16 December 2008	7292967	Change of company name from Excel-Tech Ltd. (XL TEK) to Natus Medical Incorporated, DBA Excel-Tech Ltd. (XL TEK)
25 November 2011	7635138	Re-issue due to addition of significant subcontractors as below: - Braintronics BV, The Netherlands - Manufacture - EB Neuro S.r.P Italy, - Manufacture - Creation Technologies, Canada – Manufacture - Natus Europe Gmbh (Planegg), Germany - EU Rep. and Manufacture
01 July 2013	7972894	Certificate renewal

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

Date	Reference Number	Action
20 December 2013	8091741	Addition of subcontractor Astro-Med Inc, Greenwich Ave, W.Warwick, RI. Extension and scope clarification was 'The design, development, manufacture and installation of systems for the diagnosis and monitoring of electrophysiological signals' now 'The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.'
04 November 2014	8244952	Addition of significant subcontractor Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive, Appleton. Wisconsin, 54911, USA for manufacture.
18 March 2016	8471779	Removal of significant subcontractors Astro-Med Inc located in Rhode Island, Braintronis BV located in The Netherlands and EB Neuro SpA located in Italy.
04 November 2016	8623295	Removal of significant subcontractor Natus Europe GmbH. Addition of Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland as EU Representative.
26 April 2017	8728517	Addition of Subcontractor Natus Neurology Incorporated for manufacture.
Current	8995712	Renewal Addition of manufacturing activities to Natus- Ireland